DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 7, 2014

Abbott Vascular
Vivek Thakkar
Regulatory Affairs Specialist
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K141782
Trade/Device Name: HI-TORQUE®VersaTurn Guide Wire Family
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 3, 2014
Received: July 7, 2014

Dear Mr. Thakkar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K141782

Device Names: HI-TORQUE VersaTurn Guide Wire Family

Indications for Use: The HI-TORQUE VersaTurn Guide Wire Family is intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse.

Prescription Use X OR Over-The-Counter
(Per 21 CFR 801.109) (Optional Format 1-1-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. Submitter's Name	Abbott Vascular
2. Submitter's Address	3200 Lakeside Dr. Santa Clara, CA 95054
3. Telephone	(408) 845-0899
4. Fax	(408) 845-3743
5. Contact Person	Vivek Thakkar
6. Date Prepared	June 30, 2014
7. Device Trade Name	HI-TORQUE® VersaTurn Guide Wire Family
8. Device Common Name	Guide Wire
9. Device Classification Name	Catheter Guide Wire (DQX)
10. Predicate Device Name	HI-TORQUE BALANCE MIDDLEWEIGHT ELITE (K103101, cleared February 10, 2011)

11. Device Description

The HI-TORQUE VersaTurn Guide Wire Family includes steerable guide wires offered in several configurations by various support levels, tip offerings, hydrophilic coating lengths, tip shapes and guide wire lengths.

The HI-TORQUE VersaTurn Guide Wire Family will be available with a range of tip offerings and coating lengths. These features are listed as follows:

- 4 tip offerings: *Extra Floppy (EF),Floppy (F), Soft (S), Complex (C)*
- 3 support levels: *HT VersaTurn Ultraflex, HT VersaTurn Flex, HT VersaTurn*
- 2 coating lengths: *Fully Coated (HC), Uncoated Tip (pHC)*
- 2 tip shapes: *Straight, Pre-shaped J*
- 2 lengths: *190 cm, 300cm*

The HI-TORQUE VersaTurn Guide Wire Family has a maximum diameter of 0.0142" or 0.0145" depending on the support level and is compatible with devices designed for use with 0.014" guide wires. The HI-TORQUE VersaTurn Guide Wire Family includes a shaping tool, which is clipped on to the outer packaging coil after the final assembled product has been inserted into the packaging coil. This accessory is to aid the physician in shaping the distal portion of the guide wire, if desired.

12. Indication for Use

Intended to facilitate the delivery of catheter-based interventional devices during Percutaneous transluminal angioplasty (PTA) and Percutaneous transluminal coronary angioplasty (PTCA). This guide wire may also be used with compatible stent devices.

This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse.

13. Technological Characteristics

Comparison of the new device and predicate device(s) demonstrate that the technological characteristics such as product performance, design (with minor modifications) and indications for use are substantially equivalent to the current marketed predicate devices.

14. Performance Data

In vitro bench testing, including tip tensile strength, torsional wire strength, torqueability, integrity (particulate testing), and friction testing were conducted on the modified device. The *in vitro* bench tests demonstrated that the HI-TORQUE VersaTurn Guide Wire met all acceptance criteria and performed similarly to the predicate devices. It was not necessary to repeat biocompatibility testing as testing performed on the predicate device is applicable to the HI-TORQUE VersaTurn. No new safety or effectiveness issues were raised during the testing program and therefore, the HI-TORQUE VersaTurn Guide Wire may be considered substantially equivalent to the predicate devices.

15. Conclusions

Test results from the *in vitro* bench testing conducted on the subject device demonstrate that the HI-TORQUE VersaTurn Guide Wire met all acceptance criteria and performed similarly to the predicate devices and that no new safety or effectiveness issues were raised during the testing program. Therefore, the HI-TORQUE VersaTurn Guide Wire may be considered substantially equivalent to the predicate devices.